Direct Healthcare Professional Communication

Leuprorelin-containing depot products: need to strictly follow instructions for reconstitution and administration to reduce the risk of handling errors that may result in lack of efficacy

Dear Healthcare Professional,

<Marketing authorization holder> in agreement with the European Medicines Agency and the <National Competent Authority> would like to inform you of the following:

Summary

- **Handling errors have been reported with leuprorelin-containing depot medicinal products, potentially resulting in lack of efficacy.**
- **The risk of handling errors is increased when there are multiple steps in the product reconstitution and administration process.**
- **Leuprorelin-containing depot products should be prepared, reconstituted and administered only by healthcare professionals who are familiar with these procedures.**
- **It is important to strictly follow instructions for reconstitution and administration provided in the product information.**

Background on the safety concern

Leuprorelin-containing medicines are used to treat prostate cancer, breast cancer and conditions that affect the female reproductive system (endometriosis, symptomatic uterus myomatosus, uterine fibrosis) and early puberty. They are available as daily injections or depot formulation (implants and powders and solvents for the preparation of injections). Cases of handling errors potentially resulting in lack of efficacy have been reported with depot formulations.

The present recommendations are made following an EU-wide review of this issue which concluded that the risk for handling errors is increased when there are multiple steps in the product reconstitution and administration process. To minimise the risk of handling errors, measures will be introduced, including updates to the SmPC and package leaflet to strengthen the importance that the instructions for reconstitution and administration need to be strictly followed and to recommend that these products should be only prepared and administered by healthcare professionals, who are familiar with these procedures. In case of suspected or known handling error with the medicine, patients should be monitored appropriately. In addition, the company that markets Eligard has been asked to modify the device to reduce the high number of preparation steps.

Call for reporting

Suspected adverse reactions and **any handling errors** should be reported in accordance with the national spontaneous reporting system <to be filled nationally>.

Company contacts

Annexes

<To be populated after referral outcome with measure that will be implemented>

Communication Plan for Direct Healthcare Professional Communication

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Leuprorelin-containing depot medicinal products
Marketing authorisation holder(s)	Several MAHs It is strongly encouraged that a single consistent message is sent to healthcare professionals in each EU Member State. All concerned marketing authorisation holders in each Member State are strongly encouraged to collaborate, so that a single DHPC is prepared and circulated in each Member State. The letter circulated in each Member State should cover all active substance-containing products authorised in that Member State. It is encouraged that one of the originator marketing authorisation holders (where available) in each Member State acts as the contact point for the national competent authority, on behalf of the other concerned marketing authorisation holders in the same Member State. If no originator product is marketed in the Member State, it is encouraged that one of the concerned generic companies acts as contact point for the competent authority.
Safety concern and purpose of the communication	Leuprorelin-containing depot medicinal products and handling errors resulting in lack of efficacy
DHPC recipients	HCPs involved in prescribing and handling of leuprorelin-containing depot medicinal products (e.g. urologists, medical oncologists, nurses, etc.). Target groups should be further defined on national level, depending on national health care systems.
Member States where the DHPC will be distributed	Member states where leuprorelin-containing depot medicinal products are authorised

Timetable	Date
DHPC and communication plan (in English) agreed by PRAC	14 May 2020
DHPC and communication plan (in English) agreed by CMDh	24 June 2020
Submission of translated DHPCs to the national competent authorities for review	CMDh position + 20 calendar day
Agreement of translations by national competent authorities	CMDh position + 29 calendar day
Dissemination of DHPC	CMDh position + 36 calendar days